

REMARKS

This Amendment is submitted in reply to the Final Office Action mailed on June 15, 2009. There are no fees due herewith this Amendment. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112701-00745 on the account statement.

Claims 1-8, 12-21, 31-33 and 35-37 are pending in the application. In the Office Action, Claims 1-8, 12-21, 31-33 and 35-37 are rejected under 35 U.S.C. 103(a). In response, Claims 1, 4-6 and 18-21 have been amended, Claim 17 has been canceled without prejudice or disclaimer and Claims 39-40 has been newly added. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 4, lines 13-30. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-8, 12-21, 31-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,380,252 to De Simone ("*De Simone*"), U.S. Patent Nos. 6,063,820 and 6,348,495 to Cavazza ("*Cavazza I*" and "*Cavazza II*," respectively), U.S. Publ. Nos. 2002/077349 and 2003/060503 to Hamilton ("*Hamilton I*" and "*Hamilton II*", respectively) and U.S. Patent No. 6,503,506 to Germano ("*Germano*"). In view of the claim amendments and/or for at least the reasons set forth below, Applicants respectfully disagree and request that the rejection be withdrawn.

Currently amended independent Claims 1, 4-6 and 18 recite, in part, ingestible compositions having L-carnitine and vitamin C and methods of administering same, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 4, lines 13-30. During intensive research work directed to the consequences of varying the caloric supply to individuals of different age, the present inventors surprisingly noted that among several diets administered, one diet surprisingly stimulated the lipid metabolism and thereby provided a protective effect on the condition of the skin (e.g., dry, sensible or reactive skin) while also assisting in preventing skin diseases, in particular ulcerative

dermatitis. Based on these findings, subsequent studies have been carried out, which led to the identification of the essential ingredients, including, for example, L-carnitine and an anti-oxidative component including vitamin C, which yield the effect observed. In contrast, Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims. Further, Applicants also respectfully submit that the skilled artisan would have no reason to combine the cited references because the cited references are all directed toward unrelated products having completely different objectives.

Applicants respectfully submit that the cited references fail to disclose each and every element of the present claims. For example, Applicants respectfully submit that *De Simone*, *Cavazza I*, *Cavazza II*, *Hamilton I*, *Hamilton II*, and *Germano* fail to disclose or suggest ingestible compositions having L-carnitine and vitamin C and methods of administering same, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight as required, in part, by independent Claims 1, 4-6 and 18.

Although the Patent Office asserts that “[t]he actual method step, administration of L-carnitine and anti-oxidant compositions to animals or humans in need thereof is clearly taught in the cited prior art at the levels recited in the claims,” see, Office Action, page 6, lines 14-16, Applicants respectfully disagree. Instead, Applicants respectfully submit that none of the cited references discloses or suggests ingestible compositions having L-carnitine and vitamin C and methods of administering same, wherein the amount of L-carnitine administered daily is from about 1 mg to about 1 g per kg of body weight and the amount of vitamin C administered daily is from about 0.025 mg to about 250 mg per kg of body weight as required, in part, by independent Claims 1, 4-6 and 18. Indeed, the Patent Office has not cited any disclosure reciting an ingestible composition having vitamin C, the vitamin C administered daily in an amount from about 0.025 mg to about 250 mg per kg of body weight as required, in part, by independent Claims 1, 4-6 and 18. Accordingly, Applicants respectfully submit that the cited art fails to disclose or suggest each and every element of the present claims.

Further, Applicants also respectfully submit that the skilled artisan would have no reason to combine the cited references because the cited references are all directed toward unrelated products having completely different objectives. For example, *De Simone* is entirely directed

toward methods for increasing the levels of insulin-like growth factor (IGF-1) for the therapeutic treatment of cytological disorders or diseases related to IGF-1, which promotes cell growth and differentiation. *De Simone* discloses that the administration of IGF-1 may be therapeutically useful in various morbid conditions. See, *De Simone*, column 1, line 15-column 2, line 3.

Cavazza I is entirely directed toward medical foods for treating human patients having diabetes mellitus and exhibiting symptoms such as nephropathy, retinopathy, atherosclerotic coronary disease, peripheral arteriopathies and neuropathies of the autonomic nervous system. See, *Cavazza I*, column 1, lines 4-15. Similarly, *Cavazza II* is entirely directed toward methods for treating human patients having celiac disease including, for example, inflammatory bowel disease, which is caused by a specific intolerance to gluten present in wheat, rye, barley and oat proteins included in the diet leading to dramatic changes in small intestinal mucosa and subsequent impaired absorption. See, *Cavazza II*, column 1, lines 6-15 and 63-67.

Hamilton I and *Hamilton II* are both entirely directed toward treatment of age-related conditions. For example, *Hamilton I* is entirely directed toward methods for treating age-related vision losses caused by changes in the brain including, for example, a decrease in brain weight, gyral atrophy, ventricular dilation, and selective loss of neurons within different brain regions. See, *Hamilton I*, page 1, [0003]. *Hamilton II* is entirely directed toward pet foods having specific nutritional requirements for aging pets which aims at managing risk factors for the aging pets including, for example, cancer, heart/cardiac, kidney and liver disease. See, *Hamilton II*, page 1, [0002]-[0005].

Germano is entirely directed toward compositions for treating human patients having chronic debilitating diseases such as HIV/AIDS to overcome conditions of oxidative stress, decreased lean muscle mass, decreased energy production and support immune function. See, *Germano*, Abstract. Specifically, *Germano* discloses orally administering superoxide dismutase (SOD) in combination with other antioxidant/immune support components to reduce loss of lean muscle mass and to provide energy support. See, *Germano*, Abstract.

As such, the compositions and methods of the cited references are directed toward completely unrelated products having completely unrelated objectives. Accordingly, the skilled artisan would have no reason to combine the cited references to arrive at the present claims. Indeed, it would be a stretch for the skilled artisan, aimed at stimulating the lipid metabolism in

the skin of an animal or human, to arrive at such a result by reviewing the cited references, which have widely varying applications and are directed toward entirely different objectives. Further, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there exists no reason for the skilled artisan to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Applicants respectfully submit that what the Patent Office has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Applicants also submit that if it were proper for the Patent Office to combine any number of references to arrive at the present claims simply because each reference suggests an element of the present claims, then every invention would effectively be rendered obvious. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Applicants respectfully submit that such a reason is not present in the instant case.

The Patent Office asserts that Applicants argue that the prior art references are directed to complexly unrelated products having completely unrelated objectives, but that the objectives of the administration of the compounds cited are only given limited weight and consideration when determining patentability. See, Office Action, page 6, lines 9-13. However, Applicants respectfully disagree. The present rejection is an obviousness rejection and includes the citation of several references. In such a case, where the skilled artisan would have no reason to combine the cited references, the combination of references cannot be proper. Accordingly, because the cited references are directed toward entirely different products having entirely different objectives, the skilled artisan would have no reason to combine the references at the time of the invention. In other words, the skilled artisan would not look to references disclosing increasing levels of insulin-like growth factor or treating diabetes mellitus or age-related vision loss or HIV/AIDS when attempting to derive an invention related to lipid metabolism in the skin of an animal or human.


Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1-8, 12-21, 31-33 and 35-37 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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